By the present communication, claims 1, 15, 30, 43, 58-70, 77, 98, 100, 104, 106, 110, 116, 118, 122, 124, 128, 130, 133, 134, 137, 140, 145, 146, 149, 150, 156, 157, 160, 161, and 164-171 have been amended and new claims 172-177 have been added to define Applicants' invention with with greater particularity and not in response to any properly citable reference. For example, the phrases "sealed vial" and "article of manufacture" have been introduced to define Applicants' invention with greater particularity, and to underscore the fact that Applicants' invention is a tangible object. Indeed, those skilled in the art readily recognize that a unit dosage form is an article of manufacture. No new matter is introduced as all new claim language is fully supported by the specification and original claims. For example, support for the phrase "sealed vial" is found in U.S. Patent 6,096,331 (see col. 20, lines 65-67) which is incorporated into the present specification in its entirety.

Moreover, in order to expedite prosecution and simplify examination of this application, the total number of claims has been substantially reduced. Specifically, claims 17-29, 45-57, 79-97, 102, 103, 108, 109, 114, 115, 120, 121, 126, 127, 132, 136, 142-144, 148, 152, 159, and 163 have been cancelled without prejudice. Thus, upon entry of this amendment, the total number of pending claims will be reduced from 171 to 113, and the pending claims will be 1-16, 30-44, 58-78, 98-101, 104-107, 110-113, 116-119, 122-125, 128-131, 133-135, 137-141, 145-147, 149-151, 153-158, 160-162, and 164-177.

The rejection of claims 1-171 under the judicially created doctrine of double patenting over claims 1-57 of U.S. Patent 6,096,331 is acknowledged. The provisional rejection of claims 1-16, 30-44, 58-78, 98-101, 104-107, 110-113, 116-119, 122-125, 128-131, 133-135, 137-141, 145-147, 149-151, 153-158, 160-162, 164-166, 168, and 170 under the judicially created doctrine of double patenting over claims 1-78 of co-pending Application No. 09/628,389 is also acknowledged. These rejections will be addressed in due course, once the claims are otherwise in condition for allowance (e.g., by filing a terminal disclaimer or such other action as deemed appropriate).

The rejection of claims 1-16, 30-44, 58-78, 98-101, 104-107, 110-113, 116-119, 122-125, 128-131, 133-135, 137-141, 145-147, 149-151, 153-158, 160-162, 164-166, 168, and 170 under 35 U.S.C. 102(b) as allegedly being anticipated by *Drug Facts and Comparisons* (page 3553), is respectfully traversed. Applicants' invention, as defined for example by claim 1, distinguishes over the cited reference by requiring unit dosage forms comprising a sealed vial containing a sufficient quantity of taxane to provide for administration to a subject a total dose of taxane in the range of about 30 mg/m^2 to about 1000 mg/m^2 over an administration period no greater than about three hours. *Drug Facts and Comparisons* does not disclose any unit dosage form, let alone the unit dosage forms required by the present invention.

A unit dosage form is an article of manufacture comprising a sealed vial which holds therein a specified quantity of a pharmaceutically active agent (in the present instance, the pharmaceutically active agent is taxane). Thus, those skilled in the art recognize that a unit dosage form is a tangible object. Accordingly, the present invention describes and claims articles of manufacture which contain therein a specified quantity of a taxane. In contrast, for example, *Drug Facts and Comparisons* merely sets forth a recommended dose for paclitaxel. A recommended dose is not equivalent to a unit dosage form, since a unit dosage form requires more than simply a quantity of a taxane. Clearly, *Drug Facts and Comparisons* does not disclose every element of the present claims. Accordingly, it is respectfully submitted that the rejections of claims 1-16, 30-44, 58-78, 98-101, 104-107, 110-113, 116-119, 122-125, 128-131, 133-135, 137-141, 145-147, 149-151, 153-158, 160-162, 164-166, 168, and 170 under 35 U.S.C. 102(b) over *Drug Facts and Comparisons* is not properly applied and should be withdrawn.

The rejection of claims 17-29, 45-57, 79-97, 102, 103, 108, 109, 114, 115, 120, 121, 126, 127, 132, 136, 142-144, 148, 152, 159, 163, 167, 169, and 171 under 35 U.S.C. 102(b) as allegedly being anticipated by *Drug Facts and Comparisons* (page 3558), is respectfully traversed. With respect to claims 17-29, 45-57, 79-97, 102, 103, 108, 109, 114, 115, 120, 121, 126, 127, 132, 136, 142-144, 148, 152, 159, and 163, the rejection is rendered moot by the cancellation of these claims herein. With respect to claims 167, 169, and 171, the rejection is

traversed based on the fact that Applicants' invention, as defined for example, by claim 167, distinguishes over the cited reference by requiring a method for treatment of metastatic tumors, said method comprising administration to a subject in need thereof a unit dosage form comprising a sealed vial containing a sufficient quantity of docetaxel to provide for administration to a subject a total dose of docetaxel in the range of about 30 mg/m^2 to about 1000 mg/m^2. *Drug Facts and Comparisons* does not disclose a method employing a unit dosage form.

A unit dosage form is an article of manufacture comprising a sealed vial which holds therein a specified quantity of a pharmaceutically active agent (in the present instance, the pharmaceutically active agent is a docetaxel). Thus, those skilled in the art recognize that a unit dosage form is a tangible object. Accordingly, the present invention describes and claims articles of manufacture which contain therein a specified quantity of a docetaxel. In contrast, for example, *Drug Facts and Comparisons* merely sets forth a recommended dose for docetaxel. A recommended dose is not equivalent to a unit dosage form, since a unit dosage form requires more than simply a quantity of docetaxel. Clearly, *Drug Facts and Comparisons* does not disclose every element of the present claims. Accordingly, it is respectfully submitted that the rejection of claims 167, 169, and 171 under 35 U.S.C. 102(b) is not properly applied.

The rejection of claims 1-16, 30-44, 58-78, 98-101, 104-107, 110-113, 116-119, 122-125, 128-131, 134, 135, and 137-141 under 35 U.S.C. 102(e) as allegedly being anticipated by Boni, et. al. (U.S. 5,683,715) is respectfully traversed. Applicants' invention, as defined for example by claim 1, distinguishes over the cited reference by requiring unit dosage forms comprising a sealed vial containing a sufficient quantity of taxane to provide for administration to a subject a total dose of taxane in the range of about 30 mg/m^2 to about 1000 mg/m^2 over an administration period no greater than about three hours. Boni does not disclose any unit dosage form, let alone the unit dosage forms required by the present invention. Instead, Boni merely describes a liposomal formulation of paclitaxel. A formulation of a taxane (e.g., paclitaxel) is not equivalent to a unit dosage form, since a unit dosage form requires more than simply a formulation of a taxane. Clearly, Boni does not disclose every element of the present claims.

Accordingly, it is respectfully submitted that the rejection of claims 1-16, 30-44, 58-78, 98-101, 104-107, 110-113, 116-119, 122-125, 128-131, 134, 135, and 137-141 under 35 U.S.C. 102(e) is not properly applied and should be withdrawn.

The rejection of claims 1-16, 30-44, 58-78, 98-101, 104-107, 110-113, 116-119, 122-125, 128-131, 134, 135, 137-141, 145-147, 149-151, 153, 154, 156-158, 160-162, 164-168, and 170 under 35 U.S.C. 102(e) as allegedly being anticipated by Rahman (U.S. 5,648,090) is respectfully traversed. Applicants' invention, as defined for example by claim 1, distinguishes over the cited reference by requiring unit dosage forms comprising a sealed vial containing a sufficient quantity of taxane to provide for administration to a subject a total dose of taxane in the range of about 30 mg/m^2 to about 1000 mg/m^2 over an administration period no greater than about three hours. Rahman does not disclose the unit dosage forms required by the present invention. Instead, Rahman merely describes a liposomal formulation of paclitaxel. A formulation of a taxane (e.g., paclitaxel) is not equivalent to a unit dosage form, since a unit dosage form requires more than simply a formulation of a taxane. Clearly, Rahman does not disclose every element of the present claims. Accordingly, it is respectfully submitted that the rejections of claims 1-16, 30-44, 58-78, 98-101, 104-107, 110-113, 116-119, 122-125, 128-131, 134, 135, 137-141, 145-147, 149-151, 153, 154, 156-158, 160-162, 164-168, and 170 under 35 U.S.C. 102(e) is not properly applied and should be withdrawn.

The rejection of claims 1-171 under 35 U.S.C. 103(a) as allegedly being unpatentable over *Drug Facts and Comparisons* (page 3553 or page 3558) is respectfully traversed. Applicants' invention, as defined for example by claim 1, distinguishes over the cited reference by requiring unit dosage forms comprising a sealed vial containing a sufficient quantity of taxane to provide for administration to a subject a total dose of taxane in the range of about 30 mg/m^2 to about 1000 mg/m^2 over an administration period no greater than about three hours. For the reasons cited herein, *Drug Facts and Comparisons* does not disclose or suggest any unit dosage form, let alone the unit dosage forms required by the present invention. Accordingly,

reconsideration and withdrawal of the rejection of claims 1-171 under 35 U.S.C. 103(a) are respectfully requested.

The rejections of claims 1-16, 30-44, 58-78, 98-101, 104-107, 110-113, 116-119, 122-125, 128-131, 134, 135, 137-141, 145-147, 149-151, 153, 154, 156-158, 160-162, 164-168, and 170 under 35 U.S.C. 103(a) as allegedly being unpatentable over Boni, et. al., and Rahman are respectfully traversed. Applicants' invention, as defined for example by claim 1, distinguishes over each of the cited references by requiring unit dosage forms comprising a sealed vial containing a sufficient quantity of taxane to provide for administration to a subject a total dose of taxane in the range of about 30 mg/m^2 to about 1000 mg/m^2 over an administration period no greater than about three hours. For the reasons cited herein, Boni and Rahman do not disclose or suggest any unit dosage form, let alone the unit dosage forms required by the present invention. Accordingly, reconsideration and withdrawal of the rejections under 35 U.S.C. 103(a) are respectfully requested.

The rejection of claims 1-171 under 35 U.S.C. 103(a) as allegedly being unpatenable over Boni, et. al., and Rahman in view of Li, et. al., (U.S. Patent No. 5,977,163), is respectfully traversed. Reliance on Li fails to cure the deficiencies of Boni and Rahman. Like Boni and Rahman, Li does not disclose or suggest any unit dosage form, let alone the unit dosage forms required by the present invention. Instead, Li merely discloses that docetaxel and paclitaxel are anticancer agents.

Moreover, it is respectfully submitted that there is no motivation to combine Li with Boni and/or Rahman, absent the teachings of the present invention. The Examiner's assertion (see Office Action mailed September 25, 2001, page 11, lines 14-16) that one skilled in the art would have been motivated to use any well known antitumor agent (such as docetaxel) in the formulations disclosed in Boni and/or Rahman is respectfully submitted to be irrelevant. The present invention is drawn to unit dosage forms comprising taxanes, formulations thereof, and methods for use thereof, which allow systemic administration to a human subject in need thereof

at doses and over administration periods and/or treatment cycles not previously possible. In contrast, Li merely discloses that docetaxel is an effective anticancer agent. Clearly, those skilled in the art could not arrive at the present invention by practicing the combined teachings of Boni, Rahman, and Li. Thus, it appears the Examiner has used hindsight based on the present specification in combining Li with Boni and/or Rahman. Such use of Applicants' specification is clearly improper. Accordingly, reconsideration and withdrawal of the rejection of claims 1-171 under 35 U.S.C. 103(a) are respectfully requested.

In view of the above amendments and remarks, favorable action on all claims are respectfully requested. If any matters remain to be resolved in view of this communication, the Examiner is invited to contact the undersigned at the telephone number set forth below so that a prompt disposition of this application can be achieved.

Respectfully submitted,

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Appendix

APPENDIX

1. (Amended) A unit dosage form comprising a **[container]** sealed vial containing a sufficient quantity of taxane to provide for administration to a subject a total dose of taxane in the range of about 30 mg/m^2 to about 1000 mg/m^2 over an administration period no greater than about 3 hours.

2. (Reiterated) A unit dosage form according to claim 1, wherein said total dose is in the range of about 80 mg/m^2 to about 700 mg/m^2.

3. (Reiterated) A unit dosage form according to claim 1, wherein said total dose is in the range of about 50 mg/m^2 to about 800 mg/m^2.

4. (Reiterated) A unit dosage form according to claim 1, wherein said total dose is in the range of about 50 mg/m^2 to about 800 mg/m^2.

5. (Reiterated) A unit dosage form according to claim 1, wherein said total dose is in the range of about 60 mg/m^2 to about 400 mg/m^2.

6. (Reiterated) A unit dosage form according to claim 1, wherein said total dose is in the range of about 65 mg/m^2 to about 400 mg/m^2.

7. (Reiterated) A unit dosage form according to claim 1, wherein said total dose is in the range of about 70 mg/m^2 to about 400 mg/m^2.

8. (Reiterated) A unit dosage form according to claim 1, wherein said total dose is in the range of about 85 mg/m^2 to about 375 mg/m^2.

9. (Reiterated) A unit dosage form according to claim 1, wherein said total dose is in the range of about 100 mg/m^2 to about 300 mg/m^2.

10. (Reiterated) A unit dosage form according to claim 1, wherein said subject is human.

11. (Reiterated) A unit dosage form according to claim 1, wherein the cycle time between administrations of said total dose is less than about three weeks.

12. (Reiterated) A unit dosage form according to claim 1, wherein said taxane is administered locally.

13. (Reiterated) A unit dosage form according to claim 1, wherein said taxane is administered systemically.

14. (Reiterated) A unit dosage form according to claim 1, wherein said taxane is in a non-aqueous formulation.

15. (Amended) A unit dosage form according to claim 1, wherein said taxane is **[paclitaxel]** docetaxel.

16. (Reiterated) A unit dosage form according to claim 1, wherein said taxane a paclitaxel analog.

30. (Amended) A unit dosage form comprising a **[container]** sealed vial containing a sufficient quantity of taxane to provide for administration to a subject a total dose of taxane in the range of about 40 mg/m^2 to about 800 mg/m^2 with a cycle time of no greater than about three weeks between administrations of said total dose.

31. (Reiterated) A unit dosage form according to claim 30, wherein said total dose is in the range of about 80 mg/m^2 to about 700 mg/m^2.

32. (Reiterated) A unit dosage form according to claim 30, wherein said total dose is in the range of about 50 mg/m^2 to about 800 mg/m^2.

33. (Reiterated) A unit dosage form according to claim 30, wherein said total dose is in the range of about 60 mg/m^2 to about 400 mg/m^2.

34. (Reiterated) A unit dosage form according to claim 30, wherein said total dose is in the range of about 65 mg/m^2 to about 400 mg/m^2.

35. (Reiterated) A unit dosage form according to claim 30, wherein said total dose is in the range of about 70 mg/m^2 to about 400 mg/m^2.

36. (Reiterated) A unit dosage form according to claim 30, wherein said total dose is in the range of about 85 mg/m^2 to about 375 mg/m^2.

37. (Reiterated) A unit dosage form according to claim 30, wherein said total dose is in the range of about 100 mg/m^2 to about 300 mg/m^2.

38. (Reiterated) A unit dosage form according to claim 30, wherein said subject is human.

39. (Reiterated) A unit dosage form according to claim 30, wherein said taxane is administered locally.

40. (Reiterated) A unit dosage form according to claim 30, wherein said taxane is administered systemically.

41. (Reiterated) A unit dosage form according to claim 30, wherein said taxane is in a non-aqueous formulation.

42. (Reiterated) A unit dosage form according to claim 30, wherein said taxane is in a formulation containing less than about 10% ethanol.

43. (Amended) A unit dosage form according to claim 30, wherein said taxane is **[paclitaxel]** docetaxel.

44. (Reiterated) A unit dosage form according to claim 30, wherein said taxane a paclitaxel analog.

58. (Amended) A unit dosage form comprising a **[container]** <u>sealed vial</u> containing a sufficient quantity of taxane to provide for administration to a subject a total dose of taxane in the

range of about 30 mg/m^2 to about 1000 mg/m^2, wherein said **[container]** sealed vial comprises in the range of about 4 mg to about 822 mg of said taxane.

59. (Amended) A unit dosage form according to claim 58, wherein said **[container]** sealed vial comprises in the range of about 4 mg to about 13 mg of said taxane.

60. (Amended) A unit dosage form according to claim 58, wherein said **[container]** sealed vial comprises in the range of about 13 mg to about 30 mg of said taxane.

61. (Amended) A unit dosage form according to claim 58, wherein said **[container]** sealed vial comprises in the range of about 20 mg to about 69 mg of said taxane.

62. (Amended) A unit dosage form according to claim 58, wherein said **[container]** sealed vial comprises in the range of about 45 mg to about 69 mg of said taxane.

63. (Amended) A unit dosage form according to claim 58, wherein said **[container]** sealed vial comprises in the range of about 69 mg to about 90 mg of said taxane.

64. (Amended) A unit dosage form according to claim 58, wherein said **[container]** sealed vial comprises in the range of about 69 mg to about 103 mg of said taxane.

65. (Amended) A unit dosage form according to claim 58, wherein said **[container]** sealed vial comprises in the range of about 103 mg to about 120 mg of said taxane.

66. (Amended) A unit dosage form according to claim 58, wherein said **[container]** sealed vial comprises in the range of about 103 mg to about 148 mg of said taxane.

67. (Amended) A unit dosage form according to claim 58, wherein said **[container]** sealed vial comprises in the range of about 120 mg to about 367 mg of said taxane.

68. (Amended) A unit dosage form according to claim 58, wherein said **[container]** sealed vial comprises in the range of about 148.1 mg to about 367 mg of said taxane.

69. (Amended) A unit dosage form according to claim 58, wherein said **[container]** sealed vial comprises in the range of about 367 mg to about 548 mg of said taxane.

70. (Amended) A unit dosage form according to claim 58, wherein said **[container]** sealed vial comprises in the range of about 367 mg to about 822 mg of said taxane.

71. (Reiterated) A unit dosage form according to claim 58, wherein the administration period for delivering said total dose is no greater than about 3 hours.

72. (Reiterated) A unit dosage form according to claim 58, wherein the cycle time between administrations of said taxane is less than about three weeks.

73. (Reiterated) A unit dosage form according to claim 58, wherein said subject is human.

74. (Reiterated) A unit dosage form according to claim 58, wherein said taxane is administered locally.

75. (Reiterated) A unit dosage form according to claim 58, wherein said taxane is administered systemically.

76. (Reiterated) A unit dosage form according to claim 58, wherein said taxane is in a non-aqueous formulation.

77. (Amended) A unit dosage form according to claim 58, wherein said taxane is **[paclitaxel]** docetaxel.

78. (Reiterated) A unit dosage form according to claim 58, wherein said taxane is a paclitaxel analog.

98. (Amended) A unit dosage form comprising a **[container]** sealed vial containing a sufficient quantity of taxane to provide for administration to a subject a total dose of taxane in the range of about 30 mg/m^2 to about 1000 mg/m^2, wherein said taxane remains stable for greater than about 24 hours and less than about 3 days following addition thereto of an aqueous diluent.

99. (Reiterated) A unit dosage form according to claim 98, wherein said total dose is in the range of about 70 mg/m^2 to about 400 mg/m^2.

100. (Amended) A unit dosage form according to claim 98, wherein said taxane is **[paclitaxel]** docetaxel.

101. (Reiterated) A unit dosage form according to claim 98, wherein said taxane is a paclitaxel analog.

104. (Amended) A unit dosage form comprising a **[container]** sealed vial containing a sufficient quantity of taxane to provide for administration to a subject a total dose of taxane in the range of about 30 mg/m^2 to about 1000 mg/m^2, wherein refrigeration does not adversely affect the stability of said taxane.

105. (Reiterated) A unit dosage form according to claim 104, wherein said total dose is in the range of about 70 mg/m^2 to about 400 mg/m^2.

106. (Amended) A unit dosage form according to claim 104, wherein said taxane is**[paclitaxel]** docetaxel.

107. (Reiterated) A unit dosage form according to claim 104, wherein said taxane is a paclitaxel analog.

110. (Amended) A unit dosage form comprising a **[container]** sealed vial containing a sufficient quantity of taxane to provide for administration to a subject a total dose of taxane in the range of about 30 mg/m^2 to about 1000 mg/m^2, wherein said unit dosage form is useful for the treatment of primary tumors.

111. (Reiterated) A unit dosage form according to claim 110, wherein said total dose is in the range of about 70 mg/m^2 to about 400 mg/m^2.

112. (Amended) A unit dosage form according to claim 110, wherein said taxane is **[paclitaxel]** docetaxel.

113. (Reiterated) A unit dosage form according to claim 110, wherein said taxane is a paclitaxel analog.

116. (Amended) A unit dosage form comprising a **[container]** sealed vial containing a sufficient quantity of taxane to provide for administration to a subject a total dose of taxane in the range of about 30 mg/m^2 to about 1000 mg/m^2, wherein said unit dosage form is useful for the treatment of metastatic tumors.

117. (Reiterated) A unit dosage form according to claim 116, wherein said total dose is in the range of about 70 mg/m^2 to about 400 mg/m^2.

118. (Amended) A unit dosage form according to claim 116, wherein said taxane is **[paclitaxel]** docetaxel.

119. (Reiterated) A unit dosage form according to claim 116, wherein said taxane is a paclitaxel analog.

122. (Amended) A unit dosage form comprising a **[container]** sealed vial containing a quantity of a formulation of taxane sufficient to provide for administration to a subject a total dose of taxane in the range of about 30 mg/m^2 to about 1000 mg/m^2, wherein said formulation does not leach plasticizer from administration devices used to administer said unit dosage formulation.

123. (Reiterated) A unit dosage form according to claim 122, wherein said total dose is in the range of about 70 mg/m^2 to about 400 mg/m^2.

124. (Amended) A unit dosage form according to claim 122, wherein said taxane is **[paclitaxel]** docetaxel.

125. (Reiterated) A unit dosage form according to claim 122, wherein said taxane is a paclitaxel analog.

128. (Amended) A taxane containing formulation contained within a sealed vial suitable for the delivery of a total dose of taxane in the range of about 30 mg/m^2 to about 1000 mg/m^2, with an administration period of no greater than about 3 hours.

129. (Reiterated) A formulation according to claim 128, wherein said total dose of taxane is in the range of about 80 mg/m^2 to about 700 mg/m^2.

130. (Amended) A formulation according to claim 128, wherein said taxane is **[paclitaxel]** docetaxel.

131. (Reiterated) A formulation according to claim 128, wherein said taxane is a paclitaxel analog.

133. (Amended) A taxane containing formulation contained within a sealed vial suitable for the delivery of a total dose of taxane in the range of about 80 mg/m^2 to about 700 mg/m^2, with a treatment cycle of no greater than about 3 weeks.

134. (Amended) A formulation according to claim 133, wherein said taxane is **[paclitaxel]** docetaxel.

135. (Reiterated) A formulation according to claim 133, wherein said taxane is a paclitaxel analog.

137. (Amended) A unit dosage form comprising a **[container]** sealed vial containing a sufficient quantity of taxane to allow systemic administration to a subject, employing a standard intravenous infusion set, of a total dose in the range of about 30 mg/m^2 to about 1000 mg/m^2 of said taxane.

138. (Reiterated) A unit dosage form according to claim 137, wherein said infusion set is polyolefin.

139. (Reiterated) A unit dosage form according to claim 138, wherein said polyolefin is polyethylene.

140. (Amended) A unit dosage form according to claim 137, wherein said taxane is **[paclitaxel]** docetaxel.

141. (Reiterated) A unit dosage form according to claim 137, wherein said taxane is a paclitaxel analog.

145. (Amended) A method for administration of taxane to a subject in need thereof, said method comprising administering in the range of about 30 mg/m^2 to about 1000 mg/m^2 of said taxane to said subject in a pharmaceutically acceptable formulation contained within a sealed vial with a treatment cycle no greater than about 3 weeks.

146. (Amended) A method according to claim 145, wherein said taxane is **[paclitaxel]** docetaxel.

147. (Reiterated) A method according to claim 145, wherein said taxane is a paclitaxel analog.

149. (Amended) A method for administration of taxane to a subject in need thereof, said method comprising administering in the range of about 30 mg/m^2 to about 1000 mg/m^2 of said taxane to said subject in a pharmaceutically acceptable formulation contained within a sealed vial with an administration period no greater than about 3 hours.

150. (Amended) A method according to claim 149, wherein said taxane is **[paclitaxel]** docetaxel.

151. (Reiterated) A method according to claim 149, wherein said taxane is a paclitaxel analog.

153. (Reiterated) A method for administration of taxane to a subject in need thereof, said method comprising administering in the range of about 30 mg/m^2 to about 1000 mg/m^2 of said taxane to said subject in a pharmaceutically acceptable formulation, wherein the treatment of said

subject receiving said taxane does not include the administration of agents which aid in the recovery from hematologic toxicity.

154. (Reiterated) A method according to claim 153, wherein said agent is a cytokine.

155. (Reiterated) A method for administration of docetaxel to a subject in need thereof, said method comprising administering in the range of about 30 mg/m^2 to about 1000 mg/m^2 of said docetaxel to said subject in a pharmaceutically acceptable formulation, wherein the treatment of said subject receiving said docetaxel does not include the administration of cytokines.

156. (Amended) A method for administration of taxane to a subject in need thereof, said method comprising administering a unit dosage form comprising a **[container]** sealed vial containing a sufficient quantity of taxane to provide for administration to a subject a total dose of taxane in the range of about 30 mg/m^2 to about 1000 mg/m^2, wherein said taxane remains stable for greater than about 24 hours and less than about 3 days following addition thereto of an aqueous diluent.

157. (Amended) A method according to claim 156, wherein said taxane is **[paclitaxel]** docetaxel.

158. (Reiterated) A method according to claim 156, wherein said taxane is a paclitaxel analog.

160. (Amended) A method for administration of taxane to a subject in need thereof, said method comprising administering a unit dosage form comprising a **[container]** sealed vial containing a sufficient quantity of taxane to provide for administration to a subject a total dose of taxane in the range of about 30 mg/m^2 to about 1000 mg/m^2, wherein refrigeration does not adversely affect the stability of said taxane.

161. (Amended) A method according to claim 160, wherein said taxane is **[paclitaxel]** docetaxel.

162. (Reiterated) A method according to claim 160, wherein said taxane is a paclitaxel analog.

164. (Amended) A method for treatment of primary tumors, said method comprising administration to a subject in need thereof a unit dosage form comprising a **[container]** sealed vial containing a sufficient quantity of taxane to provide for administration to a subject a total dose of taxane in the range of about 30 mg/m^2 to about 1000 mg/m^2.

165. (Amended) A method for treatment of primary tumors, said method comprising . administration to a subject in need thereof a unit dosage form comprising a **[container]** sealed vial containing a sufficient quantity of docetaxel to provide for administration to a subject a total dose of docetaxel in the range of about 30 mg/m^2 to about 1000 mg/m^2.

166. (Amended) A method for treatment of metastatic tumors, said method comprising administration to a subject in need thereof a unit dosage form comprising a **[container]** sealed vial containing a sufficient quantity of taxane to provide for administration to a subject a total dose of taxane in the range of about 30 mg/m^2 to about 1000 mg/m^2.

167. (Amended) A method for treatment of metastatic tumors, said method comprising administration to a subject in need thereof a unit dosage form comprising a **[container]** sealed vial containing a sufficient quantity of docetaxel to provide for administration to a subject a total dose of docetaxel in the range of about 30 mg/m^2 to about 1000 mg/m^2.

168. (Amended) A method for administration of taxane to a subject in need thereof, said method comprising administering a unit dosage form comprising a **[container]** sealed vial containing a sufficient quantity of taxane to provide for administration to a subject a total dose of taxane in the range of about 30 mg/m^2 to about 1000 mg/m^2, wherein said taxane does not leach plasticizer from administration devices used to administer said unit dosage formulation.

169. (Amended) A method for administration of docetaxel to a subject in need thereof, said method comprising administering a unit dosage form comprising a **[container]** sealed vial

containing a sufficient quantity of docetaxel to provide for administration to a subject a total dose of docetaxel in the range of about 30 mg/m^2 to about 1000 mg/m^2, wherein said docetaxel does not leach plasticizer from administration devices used to administer said unit dosage formulation.

170. (Amended) A method for administration of taxane to a subject in need thereof, said method comprising administering a unit dosage form comprising a **[container]** sealed vial containing a sufficient quantity of taxane to provide for administration to a subject a total dose of taxane in the range of about 30 mg/m^2 to about 1000 mg/m^2, wherein said unit dosage form confers reduced incidence of hypersensitivity as compared to a subject receiving a formulation containing a cremophor.

171. (Amended) A method for administration of docetaxel to a subject in need thereof, said method comprising administering a unit dosage form comprising a **[container]** sealed vial containing a sufficient quantity of docetaxel to provide for administration to a subject a total dose of docetaxel in the range of about 30 mg/m^2 to about 1000 mg/m^2, wherein said unit dosage form confers reduced incidence of hypersensitivity as compared to a subject receiving a formulation containing a cremophor.

172. (New) A unit dosage form of paclitaxel comprising an article of manufacture, wherein said article comprises a sealed vial containing a sufficient quantity of paclitaxel to provide for administration to a subject a total dose of paclitaxel in the range of about 40 mg/m^2 to about 800 mg/m^2 over an administration period no greater than about 3 hours.

173. (New) A unit dosage form of paclitaxel comprising an article of manufacture containing a sufficient quantity of paclitaxel to provide for administration to a subject a total dose of paclitaxel in the range of about 40 mg/m^2 to about 800 mg/m^2 over an administration period no greater than about 3 hours.

174. (New) An article of manufacture comprising paclitaxel suitable for administration to a human over an administration period no greater than about 3 hours, said article comprising a

sufficient quantity of paclitaxel to provide for administration to a subject a total dose of paclitaxel in the range of about 40 mg/m^2 to about 800 mg/m^2 over said administration period.

175. (New) An article of manufacture comprising paclitaxel suitable for administration to a human over an administration period no greater than about 3 hours, said article comprising a sealed vial containing a sufficient quantity of paclitaxel to provide for administration to a subject a total dose of paclitaxel in the range of about 40 mg/m^2 to about 800 mg/m^2 over said administration period.

176. (New) An article of manufacture comprising paclitaxel suitable for administration to a human over an administration period no greater than about 3 hours, said article comprising a sealed vial containing a sufficient quantity of paclitaxel to provide for administration to a subject a total dose of paclitaxel in the range of about 40 mg/m^2 to about 800 mg/m^2 over said administration period.

177. (New) A lyophilized taxane-containing formulation characterized by the ability to be reconstituted at concentrations greater than 1.3 mg/ml, and remaining stable for at least 3 days, wherein said taxane is docetaxel.

128. (Amended) A taxane containing formulation contained within a sealed vial suitable for the delivery of a total dose of taxane in the range of about 30 mg/m^2 to about 1000 mg/m^2, with an administration period of no greater than about 3 hours.

129. (Reiterated) A formulation according to claim 128, wherein said total dose of taxane is in the range of about 80 mg/m^2 to about 700 mg/m^2.

130. (Amended) A formulation according to claim 128, wherein said taxane is **[paclitaxel]** docetaxel.

131. (Reiterated) A formulation according to claim 128, wherein said taxane is a paclitaxel analog.

133. (Amended) A taxane containing formulation contained within a sealed vial suitable for the delivery of a total dose of taxane in the range of about 80 mg/m^2 to about 700 mg/m^2, with a treatment cycle of no greater than about 3 weeks.

134. (Amended) A formulation according to claim 133, wherein said taxane is **[paclitaxel]** docetaxel.

135. (Reiterated) A formulation according to claim 133, wherein said taxane is a paclitaxel analog.

137. (Amended) A unit dosage form comprising a **[container]** sealed vial containing a sufficient quantity of taxane to allow systemic administration to a subject, employing a standard intravenous infusion set, of a total dose in the range of about 30 mg/m^2 to about 1000 mg/m^2 of said taxane.

138. (Reiterated) A unit dosage form according to claim 137, wherein said infusion set is polyolefin.

139. (Reiterated) A unit dosage form according to claim 138, wherein said polyolefin is polyethylene.

140. (Amended) A unit dosage form according to claim 137, wherein said taxane is **[paclitaxel]** docetaxel.

141. (Reiterated) A unit dosage form according to claim 137, wherein said taxane is a paclitaxel analog.

145. (Amended) A method for administration of taxane to a subject in need thereof, said method comprising administering in the range of about 30 mg/m^2 to about 1000 mg/m^2 of said taxane to said subject in a pharmaceutically acceptable formulation contained within a sealed vial with a treatment cycle no greater than about 3 weeks.

146. (Amended) A method according to claim 145, wherein said taxane is **[paclitaxel]** docetaxel.

147. (Reiterated) A method according to claim 145, wherein said taxane is a paclitaxel analog.

149. (Amended) A method for administration of taxane to a subject in need thereof, said method comprising administering in the range of about 30 mg/m^2 to about 1000 mg/m^2 of said taxane to said subject in a pharmaceutically acceptable formulation contained within a sealed vial with an administration period no greater than about 3 hours.

150. (Amended) A method according to claim 149, wherein said taxane is **[paclitaxel]** docetaxel.

151. (Reiterated) A method according to claim 149, wherein said taxane is a paclitaxel analog.

153. (Reiterated) A method for administration of taxane to a subject in need thereof, said method comprising administering in the range of about 30 mg/m^2 to about 1000 mg/m^2 of said taxane to said subject in a pharmaceutically acceptable formulation, wherein the treatment of said

subject receiving said taxane does not include the administration of agents which aid in the recovery from hematologic toxicity.

154. (Reiterated) A method according to claim 153, wherein said agent is a cytokine.

155. (Reiterated) A method for administration of docetaxel to a subject in need thereof, said method comprising administering in the range of about 30 mg/m^2 to about 1000 mg/m^2 of said docetaxel to said subject in a pharmaceutically acceptable formulation, wherein the treatment of said subject receiving said docetaxel does not include the administration of cytokines.

156. (Amended) A method for administration of taxane to a subject in need thereof, said method comprising administering a unit dosage form comprising a **[container]** sealed vial containing a sufficient quantity of taxane to provide for administration to a subject a total dose of taxane in the range of about 30 mg/m^2 to about 1000 mg/m^2, wherein said taxane remains stable for greater than about 24 hours and less than about 3 days following addition thereto of an aqueous diluent.

157. (Amended) A method according to claim 156, wherein said taxane is **[paclitaxel]** docetaxel.

158. (Reiterated) A method according to claim 156, wherein said taxane is a paclitaxel analog.

160. (Amended) A method for administration of taxane to a subject in need thereof, said method comprising administering a unit dosage form comprising a **[container]** sealed vial containing a sufficient quantity of taxane to provide for administration to a subject a total dose of taxane in the range of about 30 mg/m^2 to about 1000 mg/m^2, wherein refrigeration does not adversely affect the stability of said taxane.

161. (Amended) A method according to claim 160, wherein said taxane is **[paclitaxel]** docetaxel.

162. (Reiterated) A method according to claim 160, wherein said taxane is a paclitaxel analog.

164. (Amended) A method for treatment of primary tumors, said method comprising administration to a subject in need thereof a unit dosage form comprising a **[container]** sealed vial containing a sufficient quantity of taxane to provide for administration to a subject a total dose of taxane in the range of about 30 mg/m^2 to about 1000 mg/m^2.

165. (Amended) A method for treatment of primary tumors, said method comprising administration to a subject in need thereof a unit dosage form comprising a **[container]** sealed vial containing a sufficient quantity of docetaxel to provide for administration to a subject a total dose of docetaxel in the range of about 30 mg/m^2 to about 1000 mg/m^2.

166. (Amended) A method for treatment of metastatic tumors, said method comprising administration to a subject in need thereof a unit dosage form comprising a **[container]** sealed vial containing a sufficient quantity of taxane to provide for administration to a subject a total dose of taxane in the range of about 30 mg/m^2 to about 1000 mg/m^2.

167. (Amended) A method for treatment of metastatic tumors, said method comprising administration to a subject in need thereof a unit dosage form comprising a **[container]** sealed vial containing a sufficient quantity of docetaxel to provide for administration to a subject a total dose of docetaxel in the range of about 30 mg/m^2 to about 1000 mg/m^2.

168. (Amended) A method for administration of taxane to a subject in need thereof, said method comprising administering a unit dosage form comprising a **[container]** sealed vial containing a sufficient quantity of taxane to provide for administration to a subject a total dose of taxane in the range of about 30 mg/m^2 to about 1000 mg/m^2, wherein said taxane does not leach plasticizer from administration devices used to administer said unit dosage formulation.

169. (Amended) A method for administration of docetaxel to a subject in need thereof, said method comprising administering a unit dosage form comprising a **[container]** sealed vial

containing a sufficient quantity of docetaxel to provide for administration to a subject a total dose of docetaxel in the range of about 30 mg/m^2 to about 1000 mg/m^2, wherein said docetaxel does not leach plasticizer from administration devices used to administer said unit dosage formulation.

170. (Amended) A method for administration of taxane to a subject in need thereof, said method comprising administering a unit dosage form comprising a **[container]** sealed vial containing a sufficient quantity of taxane to provide for administration to a subject a total dose of taxane in the range of about 30 mg/m^2 to about 1000 mg/m^2, wherein said unit dosage form confers reduced incidence of hypersensitivity as compared to a subject receiving a formulation containing a cremophor.

171. (Amended) A method for administration of docetaxel to a subject in need thereof, said method comprising administering a unit dosage form comprising a **[container]** sealed vial containing a sufficient quantity of docetaxel to provide for administration to a subject a total dose of docetaxel in the range of about 30 mg/m^2 to about 1000 mg/m^2, wherein said unit dosage form confers reduced incidence of hypersensitivity as compared to a subject receiving a formulation containing a cremophor.

172. (New) A unit dosage form of paclitaxel comprising an article of manufacture, wherein said article comprises a sealed vial containing a sufficient quantity of paclitaxel to provide for administration to a subject a total dose of paclitaxel in the range of about 40 mg/m^2 to about 800 mg/m^2 over an administration period no greater than about 3 hours.

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174. (New) An article of manufacture comprising paclitaxel suitable for administration to a human over an administration period no greater than about 3 hours, said article comprising a

sufficient quantity of paclitaxel to provide for administration to a subject a total dose of paclitaxel in the range of about 40 mg/m^2 to about 800 mg/m^2 over said administration period.

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176. (New) An article of manufacture comprising paclitaxel suitable for administration to a human over an administration period no greater than about 3 hours, said article comprising a sealed vial containing a sufficient quantity of paclitaxel to provide for administration to a subject a total dose of paclitaxel in the range of about 40 mg/m^2 to about 800 mg/m^2 over said administration period.

177. (New) A lyophilized taxane-containing formulation characterized by the ability to be reconstituted at concentrations greater than 1.3 mg/ml, and remaining stable for at least 3 days, wherein said taxane is docetaxel.